

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

**IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY
LITIGATION**

**CASE NO. 1:14-CV-01748
MDL 2545**

JUDGE MATTHEW F. KENNELLY

This Document Relates to:

***Mitchell v. AbbVie,*
Case No. 1:14-cv-09178**

**DEFENDANTS' RENEWED MOTION AND SUPPORTING MEMORANDUM
FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(b) OR,
ALTERNATIVELY, FOR A NEW TRIAL OR REMITTITUR UNDER RULE 59**

TABLE OF CONTENTS

ARGUMENT	2
I. THE JURY’S NEGLIGENCE AND STRICT LIABILITY VERDICTS CONFLICT	2
II. PLAINTIFF FAILED TO PROVE INADEQUATE WARNINGS	5
A. Reasonable Evidence of a Causal Association Did Not Exist as Required to Avoid Preemption	5
B. Plaintiff Failed to Prove Inadequate Warnings Under Oregon Law	7
III. PLAINTIFF FAILED TO PROVE CAUSATION OF USE	8
IV. PLAINTIFF FAILED TO PROVE THAT ANDROGEL CAUSED HIS HEART ATTACK OR THAT HIS INJURY WAS REASONABLY FORESEEABLE	9
A. Plaintiff Did Not Establish General Causation	9
B. Plaintiff Did Not Establish Specific Causation	11
C. Plaintiff Failed to Satisfy the Oregon Law Requirement of Showing that He Would Not Have Had a Heart Attack But For AndroGel	12
D. The Causation Instructions Were Improper	13
E. The Court Erroneously Excluded Additional Evidence Showing that AndroGel Did Not Cause Plaintiff’s Heart Attack	13
V. THE COURT SHOULD REDUCE THE DAMAGES AWARD	15
A. State Law Bars Any Punitive Damages Award	15
B. The Punitive Damages Award Violates Due Process	17
C. The Compensatory Damages Award Went Beyond the Evidence at Trial	19
D. The Punitive Damages Award Exceeded Constitutional and Illinois State Law Limitations	20
VI. THE JURY WAS CLEARLY DIVIDED AND REACHED A VERDICT THAT WAS NOT REALLY UNANIMOUS	24
CONCLUSION	25

TABLE OF AUTHORITIES

CASES	Page(s)
<i>Adams v. Fuqua Indus., Inc.</i> , 820 F.2d 271 (8th Cir. 1987)	9
<i>Allbright v. Teva Pharm. USA, Inc.</i> , No. 17-CV-61800, 2017 WL 5971720 (S.D. Fla. Dec. 1, 2017)	5
<i>Allison v. McGhan Med. Corp.</i> , 184 F.3d 1300 (11th Cir. 1999)	10
<i>Bains LLC v. Arco Prod. Co., Div. of Atl. Richfield Co.</i> , 405 F.3d 764 (9th Cir. 2005)	22
<i>In re Bayside Prison Litig.</i> , 331 F. App'x 987 (3d Cir. 2009)	22
<i>United States v. Blitch</i> , 622 F.3d 658 (7th Cir. 2010)	24
<i>BMW of N. Am., Inc. v. Gore</i> , 517 U.S. 559, 583 (1996)	22
<i>Bowman v. Corr. Corp. of Am.</i> , 350 F.3d 537 (6th Cir. 2003)	14
<i>Brown v. Burlington N. Santa Fe Ry. Co.</i> , 765 F.3d 765 (7th Cir. 2014)	12
<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001)	7
<i>United States v. Byrski</i> , 854 F.2d 955 (7th Cir. 1988)	25
<i>Chlopek v. Fed. Ins. Co.</i> , 499 F.3d 692 (7th Cir. 2007)	9
<i>Clausen v. M/V NEW CARISSA</i> , 339 F.3d 1049 (9th Cir. 2003)	11
<i>Conway v. Pac. Univ.</i> , 924 P.2d 818 (Or. 1996) (en banc)	5

<i>Dallas Ceramic Co. v. United States</i> , 598 F.2d 1382 (5th Cir. 1979)	9
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 43 F.3d 1311 (9th Cir. 1995)	10
<i>Ervin v. Johnson & Johnson, Inc.</i> , 492 F.3d 901 (7th Cir. 2007)	11
<i>Fathera v. Smyrna Police Dep’t</i> , 646 F. App’x 395 (6th Cir. 2016)	13
<i>In re Fosamax Prods. Liab. Litig.</i> , No. 06 MD 1789 JFK, 2013 WL 174416, at *4 (S.D.N.Y. Jan. 15, 2013).....	18
<i>United States v. Fossler</i> , 597 F.2d 478 (5th Cir. 1979)	24, 25
<i>Frain v. Andy Frain, Inc.</i> , 660 F. Supp. 97 (N.D. Ill. 1987)	2, 4
<i>United States v. Gabriel</i> , 597 F.2d 95 (7th Cir. 1979)	25
<i>Gen. Leaseways, Inc. v. Nat’l Truck Leasing Ass’n</i> , 830 F.2d 716 (7th Cir. 1987)	24
<i>Giles v. Wyeth, Inc.</i> , 556 F.3d 596 (7th Cir. 2009)	9
<i>Hagen v. Richardson-Merrell</i> , 697 F. Supp. 334 (N.D. Ill. 1988)	21
<i>Hazelwood v. Ill. Cent. Gulf R.R.</i> , 450 N.E.2d 1199 (Ill. App. Ct. 1983)	23
<i>Higgins v. Koch Dev. Corp.</i> , 794 F.3d 697 (7th Cir. 2015)	11
<i>Joshi v. Providence Health Sys. of Or. Corp.</i> , 149 P.3d 1164 (Or. 2006)	12, 13
<i>SEC v. Koenig</i> , 557 F.3d 736 (7th Cir. 2009)	14
<i>Kopczick v. Hobart Corp.</i> , 721 N.E.2d 769 (Ill. App. Ct. 1999)	16, 17

<i>Lawlor v. N. Am. Corp. of Ill.</i> , 983 N.E.2d 414 (Ill. 2012)	23
<i>In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.</i> , 174 F. Supp. 3d 911 (D.S.C. 2016)	9, 10
<i>Loitz v. Remington Arms Co.</i> , 563 N.E.2d 397 (Ill. 1990)	16
<i>Mendez-Matos v. Guaynabo</i> , 557 F.3d 36 (1st Cir. 2009)	21, 22
<i>Moore v. Remington Arms Co.</i> , 427 N.E.2d 608 (Ill. App. Ct. 1981)	16
<i>Moyer v. United Dominion Indus., Inc.</i> , 473 F.3d 532 (3d Cir. 2007)	15
<i>Murphy v. Smith</i> , No. 12-CV-0841-SCW, 2015 WL 13236221 (S.D. Ill. Sept. 25, 2015), <i>aff'd in part, remanded in part on other grounds</i> , 844 F.3d 653 (7th Cir. 2016), <i>aff'd</i> , 138 S. Ct. 784 (2018)	20
<i>Myers v. Ill. Cent. R. Co.</i> , 629 F.3d 639 (7th Cir. 2010)	11
<i>In re Nat'l Hockey League Players' Concussion Injury Litig.</i> , MDL No. 14-2551 SRN/BRT, 2017 WL 3142399, at *8 n.9 (D. Minn. July 24, 2017)	14
<i>Oja v. Howmedica, Inc.</i> , 111 F.3d 782 (10th Cir. 1997)	2, 3
<i>Okuda v. Wyeth</i> , No. 1:04-cv-80 DW, 2012 WL 12337860 (D. Utah July 24, 2012)	18
<i>Patton v. Country Place Condo. Ass'n</i> , No. 4-00-0008, 2000 WL 33728374 (Ill. App. Ct. July 7, 2000)	4
<i>Peabody Coal Co. v. Dir., Office of Workers' Comp. Programs</i> , 165 F.3d 1126 (7th Cir. 1999)	15
<i>Phelps v. Wyeth, Inc.</i> , 857 F. Supp. 2d 1114 (D. Or. 2012)	4
<i>Philip Morris USA v. Williams</i> , 549 U.S. 346 (2007)	19

<i>Pivot Point Int’l, Inc. v. Charlene Prod., Inc.</i> , 932 F. Supp. 220 (N.D. Ill. 1996)	23
<i>Proctor v. Davis</i> , 682 N.E.2d 1203 (Ill. 1997)	23
<i>Proffer v. Six Flags Great Am., Inc.</i> , No. 98 C 2621, 2000 WL 1741924 (N.D. Ill. Nov. 22, 2000)	21
<i>Roboserve, Inc. v. Kato Kagaku Co.</i> , 78 F.3d 266 (7th Cir. 1996)	15
<i>Rodriguez v. Stryker Corp.</i> , 680 F.3d 568 (6th Cir. 2012)	6
<i>Ross v. Black & Decker, Inc.</i> , 977 F.2d 1178 (7th Cir. 1992)	24
<i>United States v. Sanders</i> , 962 F.2d 660 (7th Cir. 1992)	25
<i>United States v. Seawell</i> , 550 F.2d 1159 (9th Cir. 1977)	25
<i>United States v. Silvern</i> , 484 F.2d 879 (7th Cir. 1973) (en banc)	24
<i>Slater v. Optical Radiation Corp.</i> , 961 F.2d 1330 (7th Cir. 1992)	5
<i>Slovinski v. Elliot</i> , 927 N.E.2d 1221 (Ill. 2010)	23
<i>State Farm Mut. Auto. Ins. Co. v. Campbell</i> , 538 U.S. 408 (2003)	17, 20, 21, 23
<i>Thompson v. Mem’l Hosp. of Carbondale</i> , 625 F.3d 394 (7th Cir. 2010)	20
<i>Townsend v. Sears, Roebuck, & Co.</i> , 879 N.E.2d 893 (Ill. 2007)	15
<i>Treaster v. Healthsouth Corp.</i> , No. CIV.A. 05-2061 JWL/GLR, 2006 WL 1580980, at *2 (D. Kan. June 5, 2006)	14
<i>Trytko v. Hubbell, Inc.</i> , 28 F.3d 715 (7th Cir. 1994)	20

<i>Utts v. Bristol-Myers Co.</i> , 251 F. Supp. 3d 644 (S.D.N.Y. 2017).....	5, 6, 7
<i>Vaughn v. G.D. Searle & Co.</i> , 536 P.2d 1247 (Or. 1975) (en banc)	8
<i>Walker v. Soo Line R. Co.</i> , 208 F.3d 581 (7th Cir. 2000)	15
<i>Walker v. Trico Mfg. Co.</i> , 487 F.2d 595 (7th Cir. 1973)	9
<i>United States v. Williams</i> , 819 F.3d 1026 (7th Cir. 2016)	24, 25
<i>In re Wright Med. Tech.</i> , No. 1:13-cv-297-WSD, 2015 WL 6690046 (N.D. Ga. Oct. 30, 2015).....	18
<i>Zazu Designs v. L’Oreal, S.A.</i> , 979 F.2d 499 (7th Cir. 1992)	23
STATUTES	
21 U.S.C. § 333(a)(1).....	22
OTHER AUTHORITIES	
21 C.F.R. §§ 201.57(c)(6)(i), 314.70(c)(6)(iii)	5
Fed. R. Evid. 801(a)	13
Fed. Judicial Ctr., Nat’l Research Council of the Nat’l Acads., <i>Reference Manual on Scientific Evidence</i> (3d ed. 2011).....	11

Numerous deficiencies pervaded Plaintiff's claims and the trial, culminating in the jury returning a confused and inconsistent verdict. The jury could not consistently find for Plaintiff on negligence and for Defendants AbbVie Inc. and Abbott Laboratories (collectively "AbbVie") on strict liability given the virtually identical issues common to the two claims. Plaintiff's negligence claim never should have even gone to the jury. *First*, Plaintiff could not establish inadequate warnings in the AndroGel label because AbbVie could not have added any warnings consistent with Food and Drug Administration (FDA) regulations, and Plaintiff presented no evidence that his claim satisfied Oregon law. *Second*, Plaintiff failed to prove that any inadequate warnings caused him to use AndroGel because both he and his prescribing physician, Dr. Canzler, confirmed that they did not rely on the label in deciding to use or prescribe AndroGel. *Third*, Plaintiff failed to demonstrate that AndroGel caused his heart attack because he showed no reliable statistical association between testosterone replacement therapy (TRT) and cardiovascular (CV) risk given the opposing weight of scientific evidence, did not adequately establish other factors indicating a causal relationship, did not identify a single epidemiological study finding increased CV risk in circumstances similar to his own, and could not rule out his well-established cardiac risk factors as the sole cause of his injury.

Nor can Plaintiff's damages award stand. State law prohibits punitive damages in light of Plaintiff's failure to show that AbbVie willfully disregarded a known and serious risk. In addition, as in Plaintiff's first trial, the punitive damages award here violated AbbVie's due process rights by resting on allegations and evidence unrelated to his claims. Furthermore, the jury's compensatory damages award went beyond the evidence introduced at trial, and the \$3 million punitive damages award—fifteen times the compensatory amount—exceeded both constitutional and Illinois state law limitations that the Court has applied.

In addition to these deficiencies, erroneous causation instructions and evidentiary rulings affected Plaintiff's negligence and punitive damages case. Finally, the repetition of a modified *Allen* charge mistakenly pressured the jury to reach a verdict after the jury made clear that "we have discussed the evidence and the facts as we understood them, but despite our best efforts, we are unable to reach a unanimous verdict."

ARGUMENT

I. THE JURY'S NEGLIGENCE AND STRICT LIABILITY VERDICTS CONFLICT

Verdicts impermissibly conflict when they reflect contrary conclusions on "virtually identical" or "essentially the same" issues. *Frain v. Andy Frain, Inc.*, 660 F. Supp. 97, 99–100 (N.D. Ill. 1987); *see Oja v. Howmedica, Inc.*, 111 F.3d 782, 790–91 (10th Cir. 1997) ("[W]hen several causes of action are identical and defended on the same ground, a verdict for the plaintiff on one cause of action and for the defendant on another is inconsistent." (internal quotation marks omitted)).

Here, the jury's negligence verdict for Plaintiff and strict liability verdict for AbbVie conflict because both claims required Plaintiff to prove the same two things: (i) unreasonable conduct as manifested through inadequate CV risk warnings in the label and (ii) causation (encompassing both causation of use and causation of Plaintiff's heart attack). *See* Instructions to the Jury at 12, 14, attached hereto as Exhibit A. By finding for AbbVie on strict liability, the jury necessarily resolved at least one of those issues in AbbVie's favor, but then resolved the same issue in *Plaintiff's* favor as part of its negligence verdict. Regardless of which of the two issues (inadequate warnings and causation) the strict liability verdict relied on, it would conflict with the negligence verdict.

The jury could not consistently reach contrary conclusions on causation because the Court gave the exact same causation instruction for both claims. *Id.* at 17. Nor could the jury

consistently reach contrary conclusions with respect to the adequacy of the warnings in the label because the Court gave virtually identical instructions on that element for both claims. With respect to strict liability, the Court instructed that AbbVie was “required to warn of dangers that it knew, or by the application of reasonable, developed human skill and foresight should have known, were inherent in the use of its product” and that “[i]n considering the adequacy of warnings, [the jury] must apply the state of scientific knowledge that was reasonably available at the time AndroGel was prescribed for Mr. Mitchell.” *Id.* at 12. With respect to negligence, the Court gave the virtually identical instruction that “AbbVie owed a duty to prescribing doctors to give reasonable warnings of the dangers that it knew or had reason to know were inherent in the use of AndroGel” and that “[i]n considering the adequacy of the warnings provided to Mr. Mitchell’s prescribing doctor, [the jury] must apply the state of scientific knowledge that was reasonably available at the time AndroGel was prescribed for Mr. Mitchell.” *Id.* at 14.

Without ruling definitively, the Court denied AbbVie’s request to query the jury about this inconsistency, reasoning that, unlike in *Konrad*, the strict liability and negligence claims did not share the common element of an “unreasonably dangerous” product. Tr. 3025:11–3026:16, attached hereto as Exhibit B. However, the virtually identical instructions for the two claims regarding the adequacy of the warnings demonstrate that they implicated the exact same issue. Thus, the jury could not logically find for AbbVie on strict liability and for Plaintiff on negligence. *See Oja*, 111 F.3d at 791–92 (holding jury’s negligent failure-to-warn verdict for plaintiff “irreconcilably” and “facially inconsistent” with its strict liability failure-to-warn verdict for defendant, despite certain “theoretical differences” between the two claims). Indeed, it makes no sense to find a defendant negligent but not strictly liable based on the same conduct.

Plaintiff cannot avoid this inconsistency by asserting that the jury found for him on negligence under an alternative failure-to-test theory. *First*, a failure-to-test theory would have also required a failure to warn because inadequate testing could not cause Plaintiff's injury unless the purportedly inadequate testing actually resulted in an inadequate warning about the results of that testing. *See Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1126 (D. Or. 2012) (“[P]laintiffs’ failure to conduct post-marketing activities and failure-to-test claims cannot be stand-alone causes of action. Rather, they are a part of the failure to warn claim.”); *Patton v. Country Place Condo. Ass’n*, No. 4-00-0008, 2000 WL 33728374, at *4 (Ill. App. Ct. July 7, 2000) (“Where plaintiffs alleged a failure to test, they have alleged an incomplete tort. The failure to test is not a negligent act in itself; rather, a failure to test leads to a failure to correct either a manufacturing defect or a failure to warn of harm resulting from the product.”). The testing theory would therefore lead to the same inconsistency as the warning theory.

Second, the Court did not instruct on any failure-to-test theory. *See* Ex. A at 14; *Frain*, 660 F. Supp. at 101 (“[T]o resolve an inconsistent verdict by reconciling it on a theory that was never present to the jury would be improper.”). Plaintiff cannot locate any such negligence theory in the general instructions on the duty to use “reasonable care” because this charge nowhere referenced testing and, instead, merely led into the “reasonable warnings” instruction specific to the pharmaceutical context.¹ Ex. A at 14. Moreover, the strict liability instructions contained analogous language regarding the general duty to avoid “unreasonably dangerous” products that similarly led into the adequate-warnings instruction applicable to the case at hand.

¹ Although AbbVie referenced negligent testing in closing, it did so only after the Court indicated that AbbVie could not limit negligent conduct exclusively to warnings, and AbbVie made clear that negligent testing still turned on the adequacy of the warnings. *See* Ex. B at 2796:9–22; *id.* at 2871:24–2872:1 (“Negligence is unreasonable conduct, including warning or testing, but it ultimately comes down to what is it that ultimately was told to Dr. Canzler.”).

Id. at 12. So if the jury found AbbVie’s testing unreasonable for purposes of the negligence claim, then its failure to make the same finding on strict liability would still be inconsistent.

Third, federal law would preclude any failure-to-test theory because the AndroGel label, which the jury found adequate on the strict liability claim, has always described the clinical studies conducted to evaluate its safety; the FDA approved this label and “concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use”; and, as Plaintiff’s experts admitted, the FDA knew about all relevant testing efforts yet “never . . . mandated additional testing prior to and through the time Mr. Mitchell had a heart attack.” Exs. 3046.2, 3048.2–3; Ex. B at 1491:1–1492:19, 1493:11–1495:5, 1516:9–19, 1901:1–21; *see Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1332–33 (7th Cir. 1992) (claim of insufficient testing “unquestionably” preempted); *Allbright v. Teva Pharm. USA, Inc.*, No. 17-CV-61800, 2017 WL 5971720, at *6 (S.D. Fla. Dec. 1, 2017) (negligent failure-to-test theory preempted). *Fourth*, for all of the reasons above, evidence from years after Plaintiff’s injury in 2012 of the FDA’s 2015 direction to conduct a new CV outcomes trial and AbbVie’s related testing efforts to the present day was prejudicial and should not have been submitted to the jury. *E.g.*, Exs. 467.3, 2627.1; Ex. B at 267:12–270:24, 985:8–986:12, 988:3–24.²

II. PLAINTIFF FAILED TO PROVE INADEQUATE WARNINGS

A. Reasonable Evidence of a Causal Association Did Not Exist as Required to Avoid Preemption

As a threshold matter, FDA regulations prohibit additional warnings, and therefore preempt state-law warnings claims, absent “reasonable evidence of a causal association.” 21 C.F.R. §§ 201.57(c)(6)(i), 314.70(c)(6)(iii); *see Utts v. Bristol-Myers Co.*, 251 F. Supp. 3d 644,

² Similarly, the negligence verdict could not have rested on an alternative negligent-misrepresentation theory because, among other things, the Court correctly did not instruct on such a theory, including the necessary “special relationship” that AbbVie would have had to owe Plaintiff “beyond the common law duty to exercise reasonable care to prevent foreseeable harm.” *Conway v. Pac. Univ.*, 924 P.2d 818, 822 (Or. 1996) (en banc) (quoting *Onita Pac. Corp. v. Trs. of Bronson*, 843 P.2d 890, 896 (Or. 1992) (en banc)).

661 (S.D.N.Y. 2017). No such reasonable evidence existed and the FDA clearly would have rejected any label change given that it considered all of the same evidence on which Plaintiff relies and has never found that it constitutes reasonable evidence of a causal association. Ex. B at 1521:15–20. Indeed, as of Plaintiff’s heart attack, the FDA had not even identified the lesser safety “signal” needed to require further testing. *Id.* at 1475:21–24, 1511:10–1512:5; *see Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) (“The law does not require a company to test for hidden risks that neither it nor the medical community had a reasonable basis to suspect.”). And under FDA Guidance, such an adverse event “safety signal” would not alone have met the reasonable-evidence standard. *See* Ex. 3094.7; *see also Utts*, 251 F. Supp. 3d at 664 (“[T]he mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events.” (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011))).

Plaintiff’s causation expert, Dr. Ardehali, suggested that reasonable evidence existed as of 2007 based on adverse event reports, one small clinical trial, and one meta-analysis that reported non-statistically significant imbalances in CV events. Ex. B at 1384:22–1385:15. But he conceded that the FDA received these same adverse event reports and has never found that they constitute reasonable evidence of a causal association. *Id.* at 1496:17–1497:1, 1521:15–20. Dr. Pence likewise agreed that “the FDA never thought there should be a warning [about CV risk] prior to 2015.” *Id.* at 1890:22–24. Both experts also acknowledged that the FDA expressly found in a 2010 review that the studies “do not support an association between TRT and an increased risk of cardiovascular events in men.” *Id.* at 1516:2–8, 1894:18–1895:1. Dr. Pence further acknowledged the FDA’s finding that “one cannot make the conclusion based on these studies that testosterone therapy increases the risk of cardiovascular disease.” *Id.* at 1896:23–

1897:2. Moreover, Plaintiff's experts agreed that "the FDA never mandated a warning or mandated additional testing prior to and through the time Mr. Mitchell had a heart attack." *Id.* at 1516:9–19, 1901:18–21.

Dr. Pence also conceded that "the FDA would not draw conclusions about drug event causality from post-marketing spontaneous reports for CV events with testosterone use." *Id.* at 1882:25–1883:4; Ex. 3258.65. And Dr. Ardehali conceded that even two years after Plaintiff's injury, the FDA Advisory Committee (AdCom) still did not find reasonable evidence of a causal association. Ex. B at 1517:23–1520:6. The mere "weak signal for possible risk" identified at that time does not suffice as a matter of law to permit a label change. *See* Ex. 3094.7; *Utts*, 251 F. Supp. 3d at 669–70 (warning claims preempted despite FDA identifying "a potential signal of a 'serious risk/new safety information'" based on adverse event reports).

Nor does the 2010 Basaria study provide reasonable evidence of a causal association. No expert offered such an opinion, and Drs. Ardehali and Pence conceded that the FDA did not find such reasonable evidence after reviewing this study. Ex. B at 1515:4–1516:12, 1896:2–1897:11.

B. Plaintiff Failed to Prove Inadequate Warnings Under Oregon Law

In addition, Plaintiff failed to provide sufficient evidence that the warnings were inadequate under state law, as Dr. Pence opined merely that AbbVie should have added a warning by 2007 "because there was reasonable evidence of a causal association." *Id.* at 1878:23–25. An assertion that AbbVie did not comply with the FDA regulation is not evidence that AbbVie provided unreasonable warnings as a matter of state law. And to the extent Dr. Pence meant to suggest that the FDA was wrong in its view that there should not be a CV warning, that suggestion is foreclosed by Plaintiff's repeated assurances that his state-law claim is not an impermissible attempt to privately enforce the Food, Drug, and Cosmetic Act (FDCA). Ex. A at 18; *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

III. PLAINTIFF FAILED TO PROVE CAUSATION OF USE

Plaintiff's and Dr. Canzler's testimony confirmed that any inadequacy in the label did not cause them to use or prescribe AndroGel. Plaintiff never even read the label. Ex. B at 1692:21–1693:2. Instead, he relied entirely on Dr. Canzler's recommendation in deciding to use AndroGel. *Id.* at 1693:3–8. Dr. Canzler, in turn, prescribed AndroGel based on his independent medical judgment and prior experience with the product. *Id.* at 1725:21–25, 1764:15–1765:3. Dr. Canzler independently weighed AndroGel's risks and benefits for Plaintiff and determined that it “was a safe product for him to use.” *Id.* at 1725:12–15, 1744:10–1745:1, 1745:15–18. Moreover, Dr. Canzler continues to prescribe AndroGel today, even after AbbVie added further CV warnings to the label in 2015, and stands by his decision to prescribe it to Plaintiff. *Id.* at 1735:19–20; Canzler Dep. at 77:10–19, attached hereto as Exhibit C.

Furthermore, any inadequate CV warnings in the label could not have caused Plaintiff to use AndroGel given that Dr. Canzler expressly warned him about CV risk. Dr. Canzler “specifically told [his AndroGel patients] that there were risks for heart attacks.” Ex. B at 1736:17–18. And with respect to Plaintiff in particular, Dr. Canzler “spoke of heart problems.” *Id.* at 1744:15–16. Dr. Canzler's independent reliance on his own medical judgment rather than the AndroGel label and his express warning about CV risk both sever any causal link between the allegedly inadequate warning and Plaintiff's injury. *See Vaughn v. G.D. Searle & Co.*, 536 P.2d 1247, 1250–51 (Or. 1975) (en banc) (holding that trial court should have granted defendant's motion for directed verdict on failure-to-warn claim due to intervening cause).

Additionally, significant evidentiary errors contributed to the jury's apparent confusion regarding causation of use. To start, notwithstanding its substantial probative value in showing that additional CV warnings would not have altered Dr. Canzler's prescription decision, the Court excluded Dr. Canzler's non-duplicative testimony that he stands by his view of AndroGel

as a safe product whose benefits outweighed its risks for Plaintiff. *Mitchell* ECF 65, *Mitchell* ECF 156; Ex. C at 46:4–12, 77:10–19. Moreover, the Court erroneously admitted the post-injury label change as relevant to “the question of what plaintiffs’ prescribing physicians would have done had AndroGel’s label been different at the time they prescribed the drug to plaintiffs”—even though Dr. Canzler’s own testimony demonstrates that the label change had no effect on his prescription decision. ECF 1966 (CMO 59) at 3–4; *see Giles v. Wyeth, Inc.*, 556 F.3d 596, 600 (7th Cir. 2009) (holding that “later warnings” “had little, if any, probative value” and that any such “probative value was substantially outweighed by the danger of confusing the jury”); *Chlopek v. Fed. Ins. Co.*, 499 F.3d 692, 700 (7th Cir. 2007) (affirming exclusion of subsequent label change as unfairly prejudicial). Exacerbating this problem, AbbVie was prevented from countering the label change with prescription trend data and expert testimony from its prescription practices expert, Dr. Khera, showing that physicians generally have not changed their prescription practices in response to the label change, as reflected in the American Urological Association’s post-label change position statement and various treatment guidelines. Ex. B at 804:4–814:2, 2464:14–2467:10.³

IV. PLAINTIFF FAILED TO PROVE THAT ANDROGEL CAUSED HIS HEART ATTACK OR THAT HIS INJURY WAS REASONABLY FORESEEABLE

A. Plaintiff Did Not Establish General Causation

As Dr. Ardehali conceded, to establish general causation, Plaintiff had to demonstrate both (i) a reliable statistical association between TRT use and CV risk and (ii) additional factors indicating a causal link. *Id.* at 1472:6–10, 1474:1–4; *see In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911, 914 (D.S.C. 2016) (“It is well

³ *See Walker v. Trico Mfg. Co.*, 487 F.2d 595, 600 (7th Cir. 1973) (upholding admission of defendant’s rebuttal evidence in products liability case); *Adams v. Fuqua Indus., Inc.*, 820 F.2d 271, 275–76 (8th Cir. 1987) (holding that district court abused its discretion in excluding defendant’s rebuttal evidence in products liability case); *Dallas Ceramic Co. v. United States*, 598 F.2d 1382, 1389 (5th Cir. 1979) (reversing based on exclusion of rebuttal evidence).

established in case law and undisputed by the parties that epidemiologists use a two-part process for determining causation.”). Plaintiff’s general causation case failed on both counts.

First, Plaintiff did not show that TRT users “have a higher incidence” of CV events, as required to demonstrate a statistical association. *Lipitor*, 174 F. Supp. 3d at 915; *accord* Ex. B at 1479:24–1480:12. As an initial matter, Dr. Ardehali should have been excluded outright under *Daubert* because he did not adequately address the weight of science showing no such statistical association, merely asserting generally that he considered these studies and they did not change his opinion. Ex. B at 1400:5–13; *see* ECF 1753. But in any event, Dr. Ardehali conceded that the incidence rate of heart attacks among TRT users did not exceed the background rate. Ex. B at 1507:9–17. And he did not identify TRT use as a causal risk factor. Moreover, the FDA has criticized the handful of studies that Plaintiff relies on and has never identified an increased risk of heart attacks among TRT users. *Id.* at 1516:2–19, 1519:11–20, 1521:21–24. To the contrary, the relevant studies demonstrate that AndroGel does not increase CV risk. *Id.* at 2703:24–2705:6. Indeed, recent studies actually show a cardioprotective effect. *Id.* at 1523:5–6, 2190:21–2191:5. Thus, Plaintiff could not establish any meaningful association, let alone the more than doubled CV risk necessary to meet the applicable preponderance-of-the-evidence standard. *See Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n.16 (11th Cir. 1999); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1320–21 (9th Cir. 1995).

Second, Plaintiff did not demonstrate additional causal factors beyond statistical association. Dr. Ardehali’s testimony on this point focused on the factor of biological plausibility. Ex. B at 1477:6–9. However, his opinion in this regard rested on limited mechanism studies from before AndroGel’s FDA approval; the FDA had access to these studies at the time of approval; AbbVie’s clinical trials actually tested and rejected two of the four

purported mechanisms; and the FDA did not even find a signal requiring further investigation based on any of the four purported mechanisms. *Id.* at 1490:19–1492:19.

B. Plaintiff Did Not Establish Specific Causation

To demonstrate specific causation, the Seventh Circuit requires experts to perform a “differential etiology.” *Myers v. Ill. Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). This methodology requires the expert to both “systematically ‘rule in’” the potential cause in question and “systematically rul[e] out” alternative causes. *Myers*, 629 F.3d at 644; *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015). Again, Plaintiff’s case failed in both regards.

First, Dr. Ardehali did not adequately “rule in” AndroGel. This first step fails for the same reasons as Plaintiff’s general causation case, and more. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057–58 (9th Cir. 2003) (“The issue at this point in the process is which of the competing causes are *generally* capable of causing the patient’s symptoms or mortality.”). As Dr. Ardehali acknowledged, to satisfy this requirement, Plaintiff had to identify a study finding a statistical association in circumstances similar to his own. Ex. B at 1536:7–18; *see Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007); Fed. Judicial Ctr., Nat’l Research Council of the Nat’l Acads., *Reference Manual on Scientific Evidence* 613 (3d ed. 2011) (“Only if the study subjects and the plaintiff are similar with respect to other risk factors will a risk estimate from a study or studies be valid when applied to an individual.”), attached hereto as Exhibit D. Yet none of Plaintiff’s studies identified such an association among individuals who, like Plaintiff, were below age 55, used TRT for more than three years, were hypogonadal, and had no prior history of CV events. Ex. B at 1536:25–1537:4, 1537:19–23, 1544:20–25, 1545:10–23, 1554:10–19. Nor did Plaintiff present evidence of CV risk for individuals who similarly used TRT only intermittently and whose testosterone levels did not normalize. *Id.* at 1545:16–19, 1579:24–1580:9, 2687:21–2688:17.

Second, Dr. Ardehali failed to adequately “rule out” alternative causes that, unlike TRT use, the scientific community has recognized as established cardiac risk factors. As Plaintiff knew at the time of his heart attack, he suffered from several cardiac risk factors, including a 34-year history of smoking, hypertension, hyperlipidemia, obesity, a family history of heart disease, and a relative lack of exercise. *Id.* at 1449:21–1453:4, 1699:7–15. Rather than adequately ruling out these factors, Dr. Ardehali conceded that they alone “were completely sufficient to cause his heart attack.” *Id.* at 1555:19–1556:21; *see Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 773 (7th Cir. 2014) (holding that plaintiff’s expert failed to establish specific causation where he did not adequately rule out alternative causes that “could have been wholly responsible for [plaintiff’s] condition”). Indeed, Dr. Ardehali would have told Plaintiff between 2010 and 2012 that he was at risk of a heart attack “any day” due to his recognized risk factors. Ex. B at 1459:24–1460:2. Because Plaintiff failed to adequately demonstrate specific causation using differential etiology, the Court should enter judgment for AbbVie.

C. Plaintiff Failed to Satisfy the Oregon Law Requirement of Showing that He Would Not Have Had a Heart Attack But For AndroGel

Under Oregon law, Plaintiff had to show that his heart attack “would not have occurred but for AbbVie’s conduct.” Ex. A at 17; *see Joshi v. Providence Health Sys. of Or. Corp.*, 149 P.3d 1164, 1169 (Or. 2006). Plaintiff failed to meet this standard given Dr. Ardehali’s concession that Plaintiff’s several recognized risk factors “were completely sufficient to cause his heart attack.” Ex. B at 1555:19–1556:21; *see* Ex. A at 17; *Joshi*, 149 P.3d at 1169 (“[T]he defendant’s conduct is not a cause of the event, if the event would have occurred without it.” (quotation omitted)). Dr. Ardehali agreed that these risk factors gave Plaintiff a 15–18% 10-year risk estimate for having a heart attack—at least double what Dr. Ardehali considers “high risk.” Ex. B at 1463:15–19, 1469:1–12. And he provided no similar calculation for TRT use. He also

would have told Plaintiff that he was at risk of a heart attack “any day” due to his risk factors. *Id.* at 1459:1–11, 1459:24–1460:2. Furthermore, Dr. Ardehali admitted that Plaintiff’s hospital records identified the same risk factors and contained nothing unusual suggesting a different cause. *Id.* at 1460:24–1462:9. Thus, Plaintiff failed to show that he would have avoided his heart attack but for AndroGel, and the Court should enter judgment for AbbVie.

D. The Causation Instructions Were Improper

The causation instructions deviated from the Oregon pattern instructions and led to jury confusion. They concluded by charging that Oregon’s but-for standard “does not require AbbVie’s conduct to be the only cause of Mr. Mitchell’s heart attack.” Ex. A at 17. But as the Court recognized, this language comes from the distinct substantial-factor test that only applies in rare cases unlike the present one, such as those involving multiple alleged tortfeasors. *Mitchell I* Tr. 3087:24–3088:6, attached hereto as Exhibit E; *Joshi*, 149 P.3d at 1165. The “only cause” language does not appear in the Oregon but-for pattern instructions. *See* Or. Unif. Civ. Jury Instruct. No. 23.01. Including it here therefore diluted the but-for causation requirement and misled the jury about what it needed to find. The negligence instruction further highlighted this erroneous language by charging, unlike the two claims upon which AbbVie prevailed, that AbbVie’s conduct only had to be “a cause” of Plaintiff’s injury. Ex. A at 12, 14, 16.

E. The Court Erroneously Excluded Additional Evidence Showing that AndroGel Did Not Cause Plaintiff’s Heart Attack

First, the Court erred in excluding testimony from Plaintiff that none of the doctors at the hospital identified AndroGel as a risk factor for his heart attack. Ex. B at 1711:20–24. The Court mistakenly ruled that such testimony constituted hearsay even though the doctors did not intend their silence on this point “as an assertion.” *Id.* at 1720:7–8; Fed. R. Evid. 801(a); *see Fathera v. Smyrna Police Dep’t*, 646 F. App’x 395, 399 (6th Cir. 2016) (holding that testimony

about “the absence of statements” was not hearsay). Moreover, Plaintiff opened the door to this testimony by testifying at length about his prior medical history, various cardiac risk factors, use of AndroGel, heart attack, and treatment at the hospital. Ex. B at 1651:6–1666:11, 1667:9–1677:5, 1681:8–18; *see SEC v. Koenig*, 557 F.3d 736, 741 (7th Cir. 2009) (“[T]o the extent genuine hearsay came in, [the opposing party] asked for it.”).

Second, the Court erred in excluding AbbVie’s statistical expert, Dr. Marais, impairing AbbVie’s ability to demonstrate that Plaintiff had not established the requisite statistical association between TRT use and CV risk. ECF 2404 (CMO 105) at 6–8. The Court reasoned that Dr. Marais’s testimony was cumulative, but testimony is not cumulative where the witness possesses “distinct areas” of expertise and testifies about “different aspects” of the issue in question. *Bowman v. Corr. Corp. of Am.*, 350 F.3d 537, 547 (6th Cir. 2003); *see, e.g., In re Nat’l Hockey League Players’ Concussion Injury Litig.*, MDL No. 14-2551 SRN/BRT, 2017 WL 3142399, at *8 n.9 (D. Minn. July 24, 2017) (“Having multiple experts address similar topics and subject matter does not render their opinions cumulative because they approach the issue from their own unique areas of expertise.”). This principle applies with particular force in cases like the present one involving “complex causation issues” that “necessitate expert witnesses with narrow, specialized areas of expertise.” *Treaster v. Healthsouth Corp.*, No. CIV.A. 05-2061 JWL/GLR, 2006 WL 1580980, at *2 (D. Kan. June 5, 2006).

No other witness brought Dr. Marais’s knowledge, experience, or perspective as a statistician. Without Dr. Marais, AbbVie could not present its full statistical critique of the studies relied on by Plaintiff, and had no one to elaborate on the statistical power of the various studies. Indeed, during Dr. French’s cross-examination, Plaintiff emphasized his lack of qualifications as a statistical expert, and the Court sustained an objection to testimony from Dr.

French about Dr. Marais’s statistical analyses of these studies. Ex. B at 2283:20–2284:18, 2385:3–8. Moreover, Dr. Marais’s absence left AbbVie without a full response to the guidance statement from the American Statistical Association that Plaintiff used extensively to cross-examine Dr. French. *See id.* at 2284:19–2290:22.⁴ Given the centrality of the causation issue and Dr. Marais’s unique expertise regarding one of AbbVie’s primary challenges to Plaintiff’s theory on that issue, the complete exclusion of his testimony prejudiced AbbVie’s case.⁵

V. THE COURT SHOULD REDUCE THE DAMAGES AWARD

A. State Law Bars Any Punitive Damages Award

AbbVie maintains that the Court should apply Oregon punitive damages law to the claims of an Oregon man who used AndroGel and had his heart attack in Oregon. *See Townsend v. Sears, Roebuck, & Co.*, 879 N.E.2d 893, 908–09 (Ill. 2007). However, even applying Illinois law, Plaintiff failed to show that punitive damages were proper. Illinois law disfavors punitive damages, and “courts must be cautious in seeing that they are not improperly or unwisely awarded.” *Roboserve, Inc. v. Kato Kagaku Co.*, 78 F.3d 266, 276 (7th Cir. 1996) (quoting *Deal v. Byford*, 537 N.E.2d 267, 272 (Ill. 1989)). Thus, “punitive damages are not awarded for mere inadvertence, mistake, errors of judgment and the like, which constitute ordinary negligence.”

⁴ Dr. Marais’s exclusion also conflicted with other rulings in this case. *First*, in originally holding that Dr. Marais could testify as an expert, the Court acknowledged his qualifications as an expert in statistics and noted that his testimony in support of AbbVie’s statistical argument went beyond Dr. French’s medical opinions. *See* ECF 1895 (CMO 46) at 14–16, 20; *id.* at 18–19 (“Dr. Marais’ causation opinions do not rely upon specialized scientific or medical judgment. Rather, they are based on his opinion that TRT is not statistically associated with plaintiffs’ alleged injuries and his conclusion that TRT is, *a fortiori*, not a cause of those injuries.”). *Second*, the Court rejected an analogous cumulativeness challenge to Dr. Marais’s testimony in the *Nolte* trial. *See Nolte* Tr. at 2736:21–2737:12 (“I mean, there’s overlap, but I don’t think—I don’t think it’s the kind of thing we’re talking about.”), attached hereto as Exhibit F. *Third*, the Court rejected AbbVie’s motion to exclude Dr. Pence despite similar overlaps in testimony regarding the adequacy of AbbVie’s testing and warning efforts, the drug approval process, the AndroGel indication, and other matters. Ex. B at 1351:16–1353:23; *see Mitchell* ECF 158.

⁵ *See Walker v. Soo Line R. Co.*, 208 F.3d 581, 592 (7th Cir. 2000) (rejecting argument that exclusion of expert causation testimony was harmless); *Peabody Coal Co. v. Dir., Office of Workers’ Comp. Programs*, 165 F.3d 1126, 1129 (7th Cir. 1999) (same); *Moyer v. United Dominion Indus., Inc.*, 473 F.3d 532, 545 (3d Cir. 2007) (same, notwithstanding that defendant introduced other evidence on the point in question).

Loitz v. Remington Arms Co., 563 N.E.2d 397, 402 (Ill. 1990) (alteration and quotation omitted). Instead, to establish the requisite “willful and wanton conduct” in a negligent failure-to-warn case, plaintiffs must demonstrate that the defendant “conscious[ly]” knew yet deliberately failed to warn of a “highly unreasonable risk of harm.” Ex. A at 21; *Loitz*, 563 N.E.2d at 402; *see Kopczick v. Hobart Corp.*, 721 N.E.2d 769, 775–76 (Ill. App. Ct. 1999).

Plaintiff could not meet this standard based on the “mere occurrence” of a few prior adverse events among TRT users and a disagreement between the parties’ experts regarding AndroGel’s safety. *Loitz*, 563 N.E.2d at 404, 407; *see Kopczick*, 721 N.E.2d at 776 (reversing punitive damages award where “the notice of prior accidents in this case does not approach the magnitude and character necessary to conclude that defendant was unable to maintain a good faith belief in the safety of its product”); *Moore v. Remington Arms Co.*, 427 N.E.2d 608, 618 (Ill. App. Ct. 1981) (same, where plaintiff’s expert failed to show defendant’s “flagrant indifference to the public safety”). AbbVie could not have consciously disregarded an unreasonable risk given that, even today, the FDA has not found reasonable evidence of a causal association based on the same adverse event reports and studies to which Plaintiff points. Ex. B at 1521:15–20. As of Plaintiff’s heart attack, the FDA had not even identified a lesser safety signal requiring further testing. *Id.* at 1475:21–24, 1511:10–1512:5. Indeed, recent studies actually show a cardioprotective effect. *Id.* at 2190:21–2191:5. The prior incidents of heart attacks reflected in the adverse event reports and studies could not have put AbbVie on notice of any unreasonable CV risk where Dr. Ardehali conceded that the heart attack incidence rate did not exceed the background rate. *Id.* at 1507:9–17; *see Loitz*, 563 N.E.2d at 404; *Kopczick*, 721 N.E.2d at 776. Nor could Dr. Ardehali’s mere disagreement with the FDA undermine AbbVie’s “good faith belief in the safety of its product.” *Kopczick*, 721 N.E.2d at 776. No jury could

reasonably find willful and wanton conduct given that the evidence, at worst, showed a reasonable debate regarding the components of Plaintiff's claim, including the adequacy of AbbVie's warnings and testing, the propriety of the indication, and the issue of causation.

B. The Punitive Damages Award Violates Due Process

The punitive damages award also violates due process by punishing AbbVie for conduct unrelated to the allegedly inadequate label upon which the jury premised liability. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages.").

The substantial majority of Plaintiff's case bore little to no relevance to him. Based on transcript page numbers, more than 80% of the evidence at trial did not relate to Plaintiff, and roughly two-thirds related to neither him nor causation. Moreover, Plaintiff's punitive damages case rested almost entirely on his theory that AbbVie engaged in a "marketing crusade" to promote AndroGel "off-label" for "age-related hypogonadism." ECF 1962 at 3–6. Yet this evidence cannot support punitive damages here because the jury specifically rejected Plaintiff's misrepresentation claim based on such marketing conduct. *See State Farm*, 538 U.S. at 422; *Kopczick*, 721 N.E.2d at 779 ("Punitive damages must derive from the wrongful conduct giving rise to a cause of action."). The FDA never found that AbbVie falsely or misleadingly promoted AndroGel off label and never took any action against AbbVie based on any ad that it ran. Ex. B at 878:19–879:4, 879:18–24. The FDA also recognized that the label's pre-2015 reference to "idiopathic" hypogonadism could encompass "age-related" hypogonadism. Ex. 3257.20.

Furthermore, Plaintiff did not link any of his marketing allegations to his injury. To the contrary, Plaintiff admitted that he did not start using AndroGel because of any AbbVie ads and had never even heard of low testosterone or AndroGel before Dr. Canzler diagnosed him and

prescribed it for him. Ex. B at 1661:12–14, 1693:16–23. Moreover, Plaintiff did not rely on any statement by AbbVie but on Dr. Canzler’s recommendation in deciding to use AndroGel. *Id.* at 1692:21–1693:8. Similarly, Dr. Canzler prescribed AndroGel based on his own medical judgement. *Id.* at 1725:21–25, 1764:22–1765:3. In addition, he did not diagnose Plaintiff with “age-related hypogonadism” and understood, regardless, that the product was not approved for that condition. *Id.* at 1786:21–1787:5, 14–16, 21–24. Indeed, given the absence of any connection to Plaintiff’s use of AndroGel or his injury, the Court should have excluded all of the marketing materials that neither plaintiff nor his physician saw or relied upon. *See* Exs. 1, 3, 5, 9, 42, 44, 52, 81, 96, 154, 177, 185, 504, 630, 667, 681, 881, 959, 966.⁶ The presentation of this irrelevant and prejudicial evidence likely contributed to the punitive damages verdict.

Nor did the other evidence upon which Plaintiff most heavily relied sufficiently relate to his negligence claim. For example, Plaintiff focused extensively on Mr. Miller’s 2003 presentation on CV risk, but this presentation occurred four years before AbbVie purportedly should have added a warning and nine years before Plaintiff’s injury; did not identify a safety signal; did not establish a need to conduct additional testing; and contained only publicly available information. Ex. B at 1006:5–8, 1153:16–19, 1155:1–4, 1158:12–22. Similarly, Plaintiff argued that the FDA lacked adequate resources, but he introduced no evidence that this purported lack of resources prevented the FDA from taking any action with respect to AndroGel. *Id.* at 843:21–844:5, 1919:16–1923:3. To the contrary, Plaintiff’s experts conceded that the FDA monitored AndroGel for a safety signal and reviewed and commented on AbbVie’s ads. *Id.* at

⁶ *See In re Wright Med. Tech.*, No. 1:13-cv-297-WSD, 2015 WL 6690046, at *12 (N.D. Ga. Oct. 30, 2015) (excluding evidence of marketing materials not viewed or relied upon by prescribing physician); *In re Fosamax Prods. Liab. Litig.*, No. 06 MD 1789 JFK, 2013 WL 174416, at *4 (S.D.N.Y. Jan. 15, 2013) (“Plaintiff may not introduce evidence of marketing or promotional materials because she has not established that she or her prescribing physicians were exposed to any such materials.”); *Okuda v. Wyeth*, No. 1:04-cv-80 DW, 2012 WL 12337860, at *1 (D. Utah July 24, 2012) (excluding “marketing evidence on which neither Plaintiff nor her physicians relied”).

843:25–844:5, 1890:6–24. Likewise, Plaintiff introduced substantial post-injury evidence relating to the 2015 AndroGel label change, the 2014 AdCom meeting that led to that change, AbbVie’s preparation for the meeting, and the FDA’s direction to conduct a CV outcomes trial, even though this evidence could not have contributed to AbbVie’s alleged negligence and Plaintiff’s injury two or more years earlier. *E.g.*, Exs. 467, 640s; Ex. B at 257:16–272:8, 985:8–986:12, 988:3–997:6. Moreover, Plaintiff repeatedly emphasized AbbVie’s sales—far out of proportion to any disputed relevance to this case. *E.g.*, Ex. B at 272:9–19, 275:11–12, 396:8–23, 1021:20–23, 1061:10–18, 1088:24–1089:2, 2489:11–18. The facts of Plaintiff’s case were buried in this blizzard of non-Plaintiff specific information. Indeed, for the same reasons, all of the foregoing evidence should have been excluded as irrelevant and prejudicial.

Just as in Plaintiff’s first trial, where the jury awarded punitive damages notwithstanding the absence of any compensatory damages, his reliance here on evidence with little connection to himself or his negligence claim resulted in the jury awarding punitive damages for conduct unrelated to his injury. The jury’s question whether it could direct the punitive damages award to a recipient other than Plaintiff illustrates this point. *Id.* at 3007:19–21. Particularly given the thousands of other plaintiffs who intend to press punitive damages claims based on the injuries that they allegedly suffered, the jury’s punitive damages award punishing AbbVie for conduct unrelated to Plaintiff’s injury violates due process. *See Philip Morris USA v. Williams*, 549 U.S. 346, 353–58 (2007) (due process bars punitive damages to punish for harm caused to others); *State Farm*, 538 U.S. at 423 (“A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business.”).

C. The Compensatory Damages Award Went Beyond the Evidence at Trial

A court must reduce a compensatory damages award when “there is no rational connection between the award and the evidence.” *Thompson v. Mem’l Hosp. of Carbondale*, 625

F.3d 394, 408 (7th Cir. 2010). The jury awarded \$150,000 in economic damages. *See Mitchell* ECF 185. But, as Plaintiff’s counsel conceded in closing, Plaintiff only experienced \$130,848 in economic damages related to his heart attack. Ex. B at 2852:5–16. The Court should therefore reduce the economic damages award to that amount. *See Trytko v. Hubbell, Inc.*, 28 F.3d 715, 724, 728 (7th Cir. 1994) (reducing compensatory damages award to conform to “the pecuniary loss suffered” and thereby avoid windfall to plaintiff); *Murphy v. Smith*, No. 12-cv-0841-SCW, 2015 WL 13236221, at *9 (S.D. Ill. Sept. 25, 2015) (“Plaintiff submitted evidence that his medical bills were \$30,983.82, but did not submit any further evidence of medical expenses. The Court accordingly reduces [the jury’s] award to the amount of the medical bills in the record, which were \$30,983.82.”), *aff’d in part, remanded in part on other grounds*, 844 F.3d 653 (7th Cir. 2016), *aff’d*, 138 S. Ct. 784 (2018).

**D. The Punitive Damages Award Exceeded
Constitutional and Illinois State Law Limitations**

Under the Due Process Clause, courts must apply “[e]xacting” review to punitive damages awards based on three guideposts: “(1) the degree of reprehensibility of the defendant’s misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.” *State Farm*, 538 U.S. at 418 (citations omitted). These guideposts require the Court to reduce the excessive \$3 million punitive damages award to \$180,848, or not more than \$700,000.

First, AbbVie did not engage in reprehensible conduct where Plaintiff failed to demonstrate indifference to public safety, targeting of Plaintiff based on financial vulnerability, conscious repeated misconduct, or any “intentional malice, trickery, or deceit.” *Id.* at 419. Any purported inadequacy in testing or warning of CV risk could not rise to this level where, as Drs.

Ardehali and Pence conceded, AbbVie and the FDA both reviewed for a CV risk signal through the time of Plaintiff's heart attack, did not identify any such signal during that time, and still, to this day, have not found reasonable evidence of a causal association. Ex. B at 1511:10–1512:5, 1521:18–20, 1890:6–24; *see Proffer v. Six Flags Great Am., Inc.*, No. 98 C 2621, 2000 WL 1741924, at *5–7 (N.D. Ill. Nov. 22, 2000) (granting summary judgment for defendant on punitive damages where plaintiff failed to show that defendant consciously “ignored obvious dangers”); *Hagen v. Richardson-Merrell*, 697 F. Supp. 334, 339–40 (N.D. Ill. 1988) (same where “the existence of [the alleged risks at issue] had not been demonstrated conclusively”). Although Plaintiff experienced a physical rather than economic injury, this factor cannot alone support reprehensibility given that the same holds true in virtually all products liability cases. *See State Farm*, 538 U.S. at 419 (“The existence of any one of these [reprehensibility] factors weighing in favor of a plaintiff may not be sufficient to sustain a punitive damages award.”).

Second, the punitive damages award bears little relation to Plaintiff's actual harm. The Supreme Court has made clear that “few awards exceeding a single-digit ratio between punitive and compensatory damages . . . will satisfy due process,” with a ratio above four coming “close to the line of constitutional impropriety.” *Id.* at 425. Furthermore, where the jury awards “substantial” compensatory damages—particularly where the award includes an amount for “emotional distress”—“a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee.” *Id.* at 425–26; *see Méndez-Matos v. Guaynabo*, 557 F.3d 36, 55 (1st Cir. 2009) (reducing punitive damages award to \$35,000 awarded in compensatory damages).

Here, the 15:1 ratio between the \$3 million punitive damages award and the combined \$200,000 compensatory damages award went far beyond what the Constitution can tolerate. The

Court should reduce the punitive damages award to match the compensatory damages award, as that amount readily qualifies as “substantial” even after reducing it to \$180,848 to comport with the evidence introduced at trial, and also includes \$50,000 for emotional distress and other non-economic damages. *See, e.g., Méndez-Matos*, 557 F.3d at 55; *In re Bayside Prison Litig.*, 331 F. App’x 987, 993–94 (3d Cir. 2009) (holding \$45,000 compensatory award “substantial” and vacating punitive damages award more than four times that amount); *Bains LLC v. Arco Prod. Co., Div. of Atl. Richfield Co.*, 405 F.3d 764, 776–77 (9th Cir. 2005) (holding \$50,000 compensatory award “substantial” and remanding for remittitur). At most, the Court should remit punitive damages to no more than \$700,000—approximately four times the compensatory damages award.

Third, the \$3 million punitive damages award far exceeds the civil penalties authorized for inadequate, or even deceptive, labeling. *See BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 583 (1996) (in reviewing punitive damages awards, courts must “accord ‘substantial deference’ to legislative judgments concerning appropriate sanctions for the conduct at issue” (quotation omitted)). For example, even viewing the label’s allegedly inadequate warning as misleading, the FDCA permits a maximum fine of “not more than \$1,000” for improper labeling, 21 U.S.C. § 333(a)(1); the Illinois Consumer Fraud and Deceptive Business Practices Act sets a maximum civil fine of only \$50,000 for false or deceptive practices, 815 Ill. Comp. Stat. 505/7(b); and the Oregon Unlawful Trade Practices Act authorizes a maximum civil penalty “not exceeding \$25,000” for a willfully unfair trade practice, Or. Rev. Stat. § 646.642(3). A punitive damages award reduced to match the compensatory damages would already greatly exceed these amounts.

Illinois law requires the same reduction. It directs courts to review the amount of a punitive damages award against “the nature and enormity of the wrong, the financial status of the

defendant, and the potential liability of the defendant.” *Deal*, 537 N.E.2d at 272; *see also Slovinski v. Elliot*, 927 N.E.2d 1221, 1228–29 (Ill. 2010) (affirming remittitur of punitive damages award to 1:1 ratio). *First*, with respect to the nature and enormity of the wrong, AbbVie complied with FDA regulations; both AbbVie and the FDA monitored for a CV risk signal through the time of Plaintiff’s heart attack; neither identified any such signal; and to this day, the FDA has not found reasonable evidence of a causal association. Ex. B at 825:16–18, 1511:10–1512:5, 1521:18–20, 1890:6–24. *Second*, AbbVie’s wealth cannot support the disproportionate punitive damages award. *See State Farm*, 538 U.S. at 427 (“The wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award.”).⁷ *Finally*, a defendant’s potential liability to others “has particular application in products liability situations” such as this one, and AbbVie faces related lawsuits from thousands of individuals. *Hazelwood v. Ill. Cent. Gulf R.R.*, 450 N.E.2d 1199, 1208 (Ill. App. Ct. 1983).⁸ Thus, Illinois state law also mandates a reduction in punitive damages to \$180,848, or not more than \$700,000. *See, e.g., Lawlor v. N. Am. Corp. of Ill.*, 983 N.E.2d 414, 432–33 (Ill. 2012) (holding that trial court abused its discretion in only reducing \$1.75 million punitive award to \$650,000, and reducing it further to \$65,000 to match compensatory damages); *Proctor v. Davis*, 682 N.E.2d 1203, 1217 (Ill. 1997) (remitting punitive damages award in products liability case to twice compensatory award); *Ross v. Black & Decker, Inc.*, 977 F.2d 1178, 1190 (7th Cir. 1992) (holding that district court abused its discretion in not reducing punitive damages award where the product at issue complied with relevant safety standards as of the dates of manufacture and sale).

⁷ *See also Zazu Designs v. L’Oreal, S.A.*, 979 F.2d 499, 508 (7th Cir. 1992) (“[The judge improperly] calculated the award as a percentage of [defendant’s] net worth—as if having a large net worth were the wrong to be deterred!”); *Pivot Point Int’l, Inc. v. Charlene Prods., Inc.*, 932 F. Supp. 220, 223 (N.D. Ill. 1996) (“Basing a decision on income and assets . . . calls into question the courts’ commitment to do equal justice to the rich and the poor.”).

⁸ *See Hazelwood*, 450 N.E.2d at 1208 (“Without this factor in our ‘excessiveness equation’, the result may well be a stampede to the courthouse, with the swiftest taking home large awards, the slow returning with nothing but their injuries, and the defendant being trampled into bankruptcy. Such a situation would be intolerable.”).

VI. THE JURY WAS CLEARLY DIVIDED AND REACHED A VERDICT THAT WAS NOT REALLY UNANIMOUS

The repetition of the modified *Allen* charge from *United States v. Silvern*, 484 F.2d 879 (7th Cir. 1973) (en banc), unintentionally pressured the jury to reach a verdict. Even if unintentional, a court may not pressure or coerce a jury into returning a verdict in the face of deadlock. See *United States v. Blich*, 622 F.3d 658, 668 (7th Cir. 2010); *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 830 F.2d 716, 730 (7th Cir. 1987). Such coercion occurs when “the court’s communications pressured the jury to surrender their honest opinions for the mere purpose of returning a verdict.” *Gen. Leaseways*, 830 F.2d at 730 (quoting *United States v. Thibodeaux*, 758 F.2d 199, 203 (7th Cir. 1985) (per curiam)). In evaluating potential coercion, courts look to the “totality of the circumstances” from the perspective of the jurors. *United States v. Williams*, 819 F.3d 1026, 1030 (7th Cir. 2016). Applying this rule, the Fifth Circuit has identified improper pressure where a jury indicated multiple times that it was deadlocked, the district court twice gave a modified *Allen* charge, and the jury returned a verdict about an hour after the second charge. See *United States v. Fossler*, 597 F.2d 478, 485 (5th Cir. 1979).

The same circumstances exist here. The jury deliberated over the course of three days and twice notified the Court that it was deadlocked—first after a day and a half of deliberation and then again the following day through a note signed by every single juror that “we have discussed the evidence and the facts as we understood them, but despite our best efforts, we are unable to reach a unanimous verdict.” Ex. B at 2960:18–23, 3014:5–8. Yet despite this deadlock, the Court overruled AbbVie’s objection to further deliberations and, for the third time at trial, provided the “modified *Allen* charge” from *Silvern*. *United States v. Gabriel*, 597 F.2d 95, 100 (7th Cir. 1979); Ex. B at 2914:4–19, 2943:19–2944:7, 3020:20–3021:17; Ex. A at 25. The Court also rejected AbbVie’s request to make clear that the jury need not ultimately reach a

verdict. Ex. B at 3019:22–3020:16. Under these circumstances, the repetition of the *Silvern* instruction in the face of the jury’s deadlock improperly conveyed that the jury had to continue deliberating until it reached a verdict. See *United States v. Sanders*, 962 F.2d 660, 677 (7th Cir. 1992) (“[M]ultiple repetitions of [the *Silvern*] instruction could conceivably overbear a jury’s independence”); *United States v. Byrski*, 854 F.2d 955, 962 n.11 (7th Cir. 1988) (describing district court’s decision to twice repeat *Silvern* instruction as “quite unusual”); *United States v. Seawell*, 550 F.2d 1159, 1163 (9th Cir. 1977) (“Repetition of [a modified *Allen*] charge, together with rejection of the jury’s second report of deadlock, is almost certain to convey the thought that by failing to come to an agreement by once again reporting themselves at impasse the jurors have acted contrary to the earlier instruction as that instruction was properly to be understood.”). Further evidencing the coercive effect of the repeated *Silvern* instruction, the jury, as in *Fossler*, returned a verdict only about an hour after receiving that charge. 597 F.2d at 485; see *Williams*, 819 F.3d at 1034 (“[I]t is somewhat more likely that a potentially coercive instruction was in fact coercive when the jury returns a verdict very quickly after receiving the instruction.”).

CONCLUSION

For the foregoing reasons, the Court should enter judgment for AbbVie or, alternatively, grant a new trial or reduce the damages award.

Dated: April 23, 2018

By: /s/ David M. Bernick

David M. Bernick

Paul, Weiss, Rifkind, Wharton &

Garrison LLP

1285 Avenue of the Americas

New York, NY 10019-6064

Tel: (212) 373-3000

dbernick@paulweiss.com

Counsel for AbbVie Inc.

CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on April 23, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David Bernick

David Bernick